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RECORD OF ORAL HEARING

U.S. PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL E. MOSELEY and JOHN KUCHARCZYK

Appeal 2010-009722
Application 09/606,137
Technology Center 3700

Oral Hearing Held: April 10, 2012

Before ERIC GRIMES, STEPHEN WALSH, and JACQUELINE WRIGHT BONILLA (via videoconference), *Administrative Patent Judges*.

APPEARANCES:

ON BEHALF OF THE APPELLANTS:
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The above-entitled matter came on for hearing on Tuesday, April 10, 2012, commencing at 1:00 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before W. Brett Bayley, Notary Public.

P R O C E E D I N G S

1:44 p.m.

THE USHER: Good afternoon. Calendar Number 20, Appeal Number 2010-009722, Mr. Litman.

JUDGE GRIMES: Thank you. Good afternoon, Mr. Litman.

MR. LITMAN: Good afternoon. Here's my card.

JUDGE GRIMES: One of our Judges is participating by videoconference here so there is a bit of a lag. So if there is a question --

MR. LITMAN: Very good.

JUDGE GRIMES: -- give him a chance.

MR. LITMAN: I speak slowly, try to, anyway. Good morning.

JUDGE GRIMES: Good afternoon. You'll have 20 minutes to make your arguments.

MR. LITMAN: Yes.

JUDGE GRIMES: And you can get started whenever you're ready.

MR. LITMAN: I'm here on appeal with regard to the technology which I am certain you're familiar with, having reviewed the case. To me, the critical issue is that all of the claims require sensing of a property in the region of a patient under examination and the use of the sense property

to provide information relating to cell chemistry that is indicative of cell activity or inactivity.

The examiner has rejected this under 35 U.S.C. 102 over Majors, and Majors does not show the substance of what this invention is, as claimed. If you look at Majors, every example but one of Majors, and every disclosure of Majors but this one example, is basically an autopsy. That is not non-invasive examination.

He takes the cells before he implants them and measures their properties, looks at them, in effect, implants them, and in all but one case kills the animals, takes the cells out and looks at them again under various diagnostic techniques.

He does not take a living animal and sense them by non-invasive activity to detect sense property relating to cell chemistry. The only example, in fact, where Majors uses a non-invasive property is in example 5 where he says with two of the surviving monkeys -- meaning he has already killed the others to test their cell status -- he performs an MRI to test for seeing a tumor or nodule. That is all. There is absolutely no use of any sensing to detect properties of cell activity.

JUDGE GRIMES: Now, if they had found a tumor, would that have indicated cell viability?

MR. LITMAN: No. What it indicates is that a tumor has grown. The cells could still be viable. But, again, we're not just looking for cell viability. This is a test procedure for non-invasively detecting specifically sensed properties of cell activity.

The cells can both form tumors -- that's an active cell, and they can form normal cells. You wouldn't want the cells to form. As both Majors says in his background and we say in the background of our invention, tumor formation is a problem with immortal cell implantation.

But what you want to do is not merely find the cells -- or, the tumors when they are at large enough state by sensing the cell activity, as we point out in the specification. You can earlier detect the activity of the cells that might lead to tumor or nodule formation because you can sense chemical activity much earlier in the state of the cell activity in the brain, rather than waiting until you can see a viable tumor.

So the properties, the method that we are performing here -- and basically what this does, if you look at some of our later claims, when there is cell activity, different cells at different kinds of activity, and they change the chemical environment within the fluids around those cells.

In specific claims, we make detection of $17O_2$ to H_217O water by MRI technology. MRI identifies the presence and the difference in those materials as a sensed property caused by cell chemistry. There are also sodium functions that are specifically recited in the claims that are nowhere to be found in Majors. Majors is nothing more than giving an MRI, a look at the brain, a look at the implant itself and see if there's a tumor. That has nothing to do with the cell activity. If he tested --

JUDGE WALSH: Mr. Litman, could you explain why the procedure Majors did with and without gadolinium was not observing a property that had to do with cell chemistry related to cell activity?

MR. LITMAN: Yes, definitely. Gadolinium is a contrast agent. When you use MRI, you get little background differentiation between the types of cells and tissues that are there. With gadolinium present, it tends to emphasize types of cells that absorb material.

Now, if you had a fully functional cell and you put gadolinium in, you'll see a clear mass, and you'll just see that clear mass over the background. You're not seeing a sense property of cell activity, you're just seeing the cells.

All this does is make the background lighter, the

foreground darker. It has nothing to do with sensing properties relating to cell chemistry that is indicative of cell activity or inactivity. All we're doing is making a more contrasting image.

The other techniques, such as MRI and looking for responses in particular wavelengths due to the chemistry that is produced by the cell is totally different than merely taking an image of the cell. That's all he does in this one example is take an image of a cell.

What we have specifically and in more detail in the dependent claims for the type of cell activity chemistry that we're examining is a sensed property -- and that is a variation in the wavelengths and frequencies of the responses in the area due to changes in chemistry caused by cell activity -- that is wholly different, wholly different from just looking and saying there is a tumor, there is not a tumor.

JUDGE BONILLA: Let me ask you about claim 5, because that one doesn't have a lot of the language that you're talking about in a dependent claim.

MR. LITMAN: I'm sorry, I can't hear you.

JUDGE BONILLA: I'm sorry, claim 5, which is the sensing of property.

MR. LITMAN: All right.

JUDGE BONILLA: What if sensing a property is sensing a tumor?

MR. LITMAN: All right, let me look at claim 5. I've got an awful lot of pages here, okay.

JUDGE BONILLA: It says, sensing a property within a region. So let's say sensing a tumor within a region, tumor being a property --

MR. LITMAN: All right.

JUDGE BONILLA: -- is invaded from sensing property to indicate cell viability where that property is resulting from, for example, cell growth or cell death, cell activity --

MR. LITMAN: And, remember, this is -- cell viability indicated by a property in cell chemistry resulting from an event selected from. What this is, this is cell chemistry. This is not merely the cell itself. This is sensing a change in the environment due to changes in chemistry in that environment due to changes in cell activity. When cells die, they give off different materials.

JUDGE BONILLA: How do you respond to --

MR. LITMAN: And you sense that.

JUDGE BONILLA: How do you respond to the statement that cell chemistry could just be, you know,

active cell growth like you would see in a tumor?

MR. LITMAN: I'm sorry, I still can't hear you.

JUDGE BONILLA: How would you respond to the idea that cell chemistry could even be just a massive doubling of cells, like you would see in a tumor?

MR. LITMAN: Doubling the cells? That's merely a change in size. It has nothing to do with a change in cell chemistry. All he is doing is looking, and all of his examinations of change in the growth of the cell were done postmortem.

The only example where he does anything *in vivo* is looking to see if a tumor is there or not. At no time does he ever say, I am going to examine the environment around the cells, sense properties as a result of this external stimulations, and determine changes in chemistry in that environment which are indicative of changes in cell chemistry.

If all you were doing was saying, I'm going to take an MRI, the cells are larger now, great, or there's tumors there, great, that's totally different from what we're doing. And this also gives a much earlier ability to respond to deficiencies in implantation.

One of the big problems of implantation is, you put in the material and you have to wait until the tumor

grows before you can see it, and by then your patient has lost all the benefits of the implantation and you have to have another surgery.

If you go in at this stage where you can't even visualize the tumor and you see the change in cell chemistry, you can do an intervention at that point with subsequent chemicals, additional medical treatment where you've got a better-performing implantation.

This is wholly different from waiting until your patient is dying to see that he's got a problem with this implantation. This measures gigagram levels of drugs in the system that are indicative of changes in the cell chemistry so you can monitor it within invasive procedures on the patient.

This is far, far different from merely cutting out the patient's brain to see if the cell implants work, or taking an MRI to see if you've got visible tumors and you know this implantation has failed. And all the claims are so limited.

And remember also there are those specific claims to the specific types of variations in cell chemistry that are being measured that have not been touched. Local lactate levels, local glucose turnover, local phosphorus high energy metabolite concentrations, local F-19 labeled

metabolites, alterations in tissue sodium and changes in conversion rates of O_2 to H_2O. Nothing in Majors approaches that.

Nothing in the secondary teaches that that can be done by an external non-invasive procedure. This is definitely novel and clearly not obvious from the teaching and the references. And every claim contains at least sensing of a property and use of that sense data to provide information relating to cell chemistry that is indicative of cell activity or inactivity. It's not merely looking to see if they're growing or not growing or if it's a tumor or not a tumor. It's measuring the resultant environmental chemistry around those cells to determine what activity those cells are having.

JUDGE GRIMES: You have referred to the claim process as being non-invasive.

MR. LITMAN: Yes.

JUDGE GRIMES: That, I assume, follows from non-destructively observing a region?

MR. LITMAN: Yes, non-destructively observing, because to invade you have to destroy. You can't get to brain cells or implant cells without -- and sense the way Majors is without taking the cells out. Majors always biopsies the material to test except in that one example

where the only thing he is testing for is the presence of nodules or tumors.

And Morcose also adds absolutely nothing to what the failures are of Majors. And notice that Majors emphasizes in his own disclosure that what he is doing is -- where is the specific language that the examiner even quoted, prior to implantation, the viabilities of cells may be assessed.

That's great, but it has no significance with regard to what the viability of the cells are after implantation, which is when it's most critical. All that Majors does is detect the final extreme deviation in the growth of tumors and nodules. That is too far down the line to be useful to the majority of patients where any problems are going on.

JUDGE BONILLA: How broadly should we interpret the terms observing or sensing or using, and can those be eyeballed?

MR. LITMAN: I'm sorry, I can't hear. I've got my hearing aids on, but that's --

JUDGE BONILLA: I wasn't speaking very clearly. How broadly should we interpret the step terms, so observing or sensing or using data, can those be eyeballed, for example, on the skin?

MR. LITMAN: You can't eyeball changes in cell chemistry in the environment. There's no way you can eyeball it. The only way you can eyeball it is by having a monitor screen as a result of the MRI stimulation, and with that stimulation having frequency responses being displayed that are indicative of the specific cell chemistry changes.

There isn't a single type of observation that would be made for these different cell chemistries because they would appear at different frequencies, different types of responses. You cannot observe cell chemistry any more than you can observe, you know, oxygen and hydrogen, water splitting up into OH and H inside of a water bottle. You can't see it.

JUDGE BONILLA: So you assume that one of the steps in the claim is actually observing cell chemistry?

MR. LITMAN: Yes. It is a definitive step that there be the active effort of --

JUDGE BONILLA: Because the claim --

MR. LITMAN: -- nondestructively observing.

JUDGE BONILLA: -- that we're seeing, using data to indicate cell viability, and this is -- cell viability is indicated by the cell chemistry. And you interpret that to mean that they are actually measuring cell chemistry in some way? Am I reading that correctly?

MR. LITMAN: I think a little more broadly than I would interpret it. It's nondestructively observing a region of a patient where the cells have been transplanted, and it's sensing a property within said region, and that property being directly related to cell chemistry resulting from classes of events. There has to -- the cell chemistry has to result from cell activity. This is -- and growth itself is not a cell chemistry property that you sense.

JUDGE BONILLA: So sensing a property is sensing the cell chemistry?

MR. LITMAN: Yes, you sense -- exactly. Okay. All right, I know I got one comment I wanted to make on Morcose, but I will in a second here. Oh, okay, also the specific methods are not shown in Morcose either. He has absolutely no instruction or evidence that would teach the obviousness of the use of the sensing of those kinds of properties for any purpose whatsoever.

JUDGE GRIMES: All right, I think we understand your argument.

MR. LITMAN: I hope so.

JUDGE GRIMES: The panel has no more questions.

MR. LITMAN: If I may put in the record, this is approximately my 450th appeal to the Patent and Trademark Office.

JUDGE GRIMES: Wow.

MR. LITMAN: And almost to the day the 40th year of my going into private practice after leaving the Patent Office, and I am now going to be taking a position with the University of Nevada Las Vegas in their intellectual property transfer department, as well as continuing my practice. So, if I may quote Bob Dylan, if you're not working to be reborn, you're living to die. So here we go.

JUDGE GRIMES: Best of luck.

MR. LITMAN: Thank you all.

JUDGE GRIMES: We're off the record.

[WHEREUPON, the proceedings were concluded at 2:02 p.m.]

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